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**UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF CALIFORNIA**

SYLVESTER DUMAS; BEVERLY
 MATHERNE, individually, and as
 Executor of the Estate of ASHLEY
 JOSEPH MATHERNE, deceased;
 DONALD TINDALL; GLENDA
 BALLARD; RHEISSIE L. BALLARD,
 JR.; THOMAS MOYERS; KIMBERLY
 THOMPSON; and DOUGLAS
 THOMPSON;

Plaintiffs,

v.

JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN RESEARCH AND
 DEVELOPMENT, LLC; JOHNSON &
 JOHNSON; JANSSEN ORTHO, LLC;
 MITSUBISHI TANABE PHARMA
 HOLDINGS AMERICA, INC.;
 MITSUBISHI TANABE PHARMA
 DEVELOPMENT AMERICA, INC.;
 TANABE RESEARCH
 LABORATORIES U.S.A., INC.;
 MITSUBISHI TANABE PHARMA
 CORP.; MCKESSON CORPORATION;
 and DOES 1-50;

Defendants.

Case No. 3:16-cv-00647-L-WVG

Hon. M. James Lorenz

**REPLY MEMORANDUM IN
 SUPPORT OF DEFENDANTS
 JOHNSON & JOHNSON, JANSSEN
 RESEARCH & DEVELOPMENT,
 LLC, JANSSEN ORTHO, LLC,
 TANABE RESEARCH
 LABORATORIES, U.S.A., INC., AND
 MITSUBISHI TANABE PHARMA
 DEVELOPMENT AMERICA, INC.'S
 MOTION TO DISMISS
 PLAINTIFFS' FIRST AMENDED
 COMPLAINT PURSUANT TO
 FEDERAL RULES OF CIVIL
 PROCEDURE 12(b)(2) AND 12(b)(6)**

HEARING: July 25, 2016
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REPLY MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION.

Plaintiffs fail to address many of Defendants’ arguments, concede other arguments, and generally misstate the law. The Court should dismiss the First Amended Complaint (“FAC”) in its entirety.

II. ARGUMENT.

A. The Court Should Dismiss All Of Plaintiffs’ Claims As Against Johnson & Johnson, Ortho, And MTPD For Lack Of Personal Jurisdiction.

Johnson & Johnson, Ortho, and MTPD are not subject to general jurisdiction. *See* Defs.’ Mem. at 5–6. Plaintiffs do not disagree. *See generally* Pls.’ Opp’n (failing to address Defendants’ general jurisdiction arguments). Nor have Plaintiffs demonstrated that Johnson & Johnson, Ortho, and MTPD are subject to specific jurisdiction.

As an initial matter, Plaintiffs do *not* dispute the evidence before the Court concerning Johnson & Johnson—to wit, that Johnson & Johnson is a holding company that neither manufactured nor sold Invokana. *Compare* Defs.’ Mem. at 6–7 & ns. 4–5 (discussing *Brazil*, *Androphy*, and *Robinson*), with *generally* Pls.’ Opp’n (failing to address holding company argument). Their failure to do so amounts to a concession that, on this basis, Johnson & Johnson is *not* subject to specific jurisdiction. *See, e.g., Silva v. U.S. Bancorp*, 2011 WL 7096576, at *3 (C.D. Cal. Oct. 6, 2011) (“It is well understood . . . that when a plaintiff files an opposition to a motion to dismiss addressing only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.” (quoting *Hopkins v. Women’s Div., Gen. Bd. of Global Ministries*, 238 F. Supp. 2d 174, 178 (D.D.C. 2002))). Plaintiffs cannot avoid *Brazil* on the grounds that it involved “questions” of Georgia law. Pls.’ Opp’n at 7. The reasons that led the *Brazil* court to dismiss Johnson & Johnson had nothing to do with Georgia law and apply equally here. *See also Holland Am. Line Inc. v. Wärtsilä N. Am., Inc.*, 485 F.3d 450, 459 (9th Cir. 2007) (affirming dismissal of holding company for lack of personal jurisdiction because it “has not put *any* products into the stream of commerce”).

Further, Plaintiffs do not explain why the court’s dismissal of Johnson & Johnson for lack of personal jurisdiction in *Fleming* also does not support dismissal of their claims against Johnson & Johnson, Ortho, and MTPD. Like the plaintiff in *Fleming*, Plaintiffs here do not allege any *facts* showing that Johnson & Johnson, Ortho, or MTPD controlled the flow of Invokana into California, nor do they allege any *facts* to connect Johnson & Johnson’s purported “collaboration” on the design and development of Invokana to that flow. *See* Defs.’ Mem. at 7–8, 12–13. Instead, Plaintiffs rely on conclusory allegations concerning undifferentiated conduct by the collective “Defendants.” Pls.’ Opp’n at 8. But that is improper. *See, e.g., Aaron v. Aguirre*, 2007 WL 959083, at *16 & n.6 (S.D. Cal. Mar. 8, 2007) (“[U]ndifferentiated pleading against multiple defendants is improper.”); *see also* Doc. 15–1 at 10 n.11 (discussing additional authority). Nor is it sufficient to argue that *Fleming* involved “questions” of Tennessee law. Pls.’ Opp’n at 7. Like courts in Tennessee, the Ninth Circuit and Central District of California have endorsed the very same stream-of-commerce-plus test that led the *Fleming* court to dismiss Johnson & Johnson for lack of personal jurisdiction. *See* Defs.’ Mem. at 7 n.7.

Instead of addressing Defendants’ arguments, Plaintiffs assert—without *any* legal support—that Johnson & Johnson is subject to specific jurisdiction because it is the alter ego of Janssen, JRD, and Ortho. *See* Pls.’ Opp’n at 9–10. They also assert—again, without *any* support—that Johnson & Johnson, Ortho, and MTPD are subject to specific jurisdiction because (1) they acted “in concert” with the “California defendants” (*i.e.*, TRL and McKesson) and (2) Plaintiffs’ claims are properly joined, thereby creating a “California nexus.”¹ *Id.* at 7–9, 11–12. None of these arguments has merit.

Plaintiffs’ alter-ego theory fails for two reasons. First, Plaintiffs do not sufficiently allege that Janssen, JRD, and Ortho have any California contacts that are capable of being imputed to Johnson & Johnson. *See generally* FAC. Second, Plaintiffs’ theory rests

¹ Plaintiffs also argue that “Defendants claim that Plaintiffs make no allegations specifically against Ortho.” Pls.’ Opp’n at 12. In fact, Defendants argued that Plaintiffs could not establish specific jurisdiction over Ortho. *See* Defs.’ Mem. at 10–12. Yet Plaintiffs have done nothing to demonstrate that this Court can exercise personal jurisdiction over Ortho.

solely on the conclusory allegations in paragraphs 63, 64, and 65 of the FAC concerning Johnson & Johnson’s purported “control” over Janssen, JRD, and Ortho. *See* Pls.’ Opp’n at 9–10. But as explained, those conclusory allegations do *not* warrant the imputation of Janssen, Ortho, or MTPD’s purported California contacts to Johnson & Johnson. *See* Defs.’ Mem. at 10 n.9 (discussing *Los Gatos*). Plaintiffs cite *no* authority to the contrary.

Plaintiffs’ acting-in-concert theory fares no better than their alter-ego theory. A non-resident defendant is *not* subject to personal jurisdiction for alleged conduct “in concert” with a forum defendant in the absence of an actionable conspiracy claim. *See* *Murphy v. Am. Gen. Life Ins. Co.*, 2015 WL 4379834, at *8 (C.D. Cal. July 15, 2015) (“It has long been recognized that personal jurisdiction over a defendant . . . may be present in a forum so long as an actionable conspiracy is pled and a substantial act in furtherance of the conspiracy is performed in the forum state.” (internal citations omitted)). But Plaintiffs have *not* alleged a claim for civil conspiracy. *See generally* FAC. In fact, the words “conspire” and “conspiracy” do not appear anywhere in the FAC. *See generally id.* Thus, Johnson & Johnson, Ortho, and MTPD are not subject to personal jurisdiction based on Plaintiffs’ unsupported acting-in-concert theory.²

Nor can the Non-California Plaintiffs piggyback on the specific jurisdiction that exists over Janssen with respect to the claims of Mr. Dumas (*i.e.*, the sole California plaintiff). While Plaintiffs argue that their claims are properly joined (*see* Pls.’ Opp’n at 11), they plainly are not. Joinder is permissible only if plaintiffs’ claims arise out of the same transaction or occurrence. *See* Fed. R. Civ. P. 20(a)(1)(A); Cal. Code Civ. Proc. § 378. While Plaintiffs’ claims share a common factor—*i.e.*, the alleged use of Invokana—they do *not* arise out of the same transaction or occurrence. After all, Plaintiffs experienced *different* injuries at *different* times after *different* physicians prescribed Invokana based on Plaintiffs’ unique medical histories. Courts in California and across

² Further, MTPD had *no* involvement in the licensing of Invokana, as Plaintiffs claim. *Compare* Defs.’ Mem. at 12–13, *with* Pls.’ Opp’n at 12–13. The Court may take judicial notice of the Prescribing Information for Invokana, which shows that MTPC—not MTPD—is involved in licensing of the drug. *See* Defs.’ Mem. at 12 & n.11.

the country have confirmed that claims such as these are *not* properly joined.³

Further, even if Plaintiffs' claims were properly joined, joinder rules *cannot* extend a court's jurisdiction beyond the limits of due process. *See Lincoln Prop. Co. v. Roche*, 546 U.S. 81, 90, 91 (2005) (explaining that federal joinder rules do not affect federal court jurisdiction, citing FED. R. CIV. P. 82); *Level 3 Commc'ns, LLC v. Ill. Bell Tel. Co.*, 2014 WL 50856, at *3 (E.D. Mo. Jan. 7, 2014) ("It is well-established that the requirement for personal jurisdiction cannot be bypassed by proving proper joinder."), *order vacated in part on other grounds on recons.*, 2014 WL 1347531 (E.D. Mo. Apr. 4, 2014). And due process *requires* that there be "specific jurisdiction for *each claim* asserted against the defendant." 5B Wright & Miller, Fed. Prac. & Civ. Proc. Civ. § 1351, n.30 (3d ed. 2015) ("[I]f separate claims are pled, specific personal jurisdiction must independently exist for each claim and the existence of personal jurisdiction for one claim will not provide the basis for another claim."). The Ninth Circuit has long recognized that specific jurisdiction is claim-specific. *See Data Disc, Inc. v. Sys. Tech. Assocs., Inc.*, 557 F.2d 1280, 1289 n. 8 (9th Cir. 1977).⁴

Because a single plaintiff must establish personal jurisdiction over *each claim*, it necessarily follows that *each plaintiff* must establish personal jurisdiction as to *each of his or her own claims*. *See, e.g., In re Zofran (Ondansetron) Prods. Liab. Litig.*, 2016 WL 2349105, at *5 (D. Mass. May 4, 2016) (holding that defendants' marketing and sales of Zofran in Missouri do not confer specific jurisdiction over claims of plaintiffs who used drug and were injured in Delaware, North Carolina, and Pennsylvania); *In re*

³ *See, e.g., David v. Medtronic, Inc.*, 237 Cal. App. 4th 734, 741 (2015) (finding joinder improper because plaintiffs had "different surgeries, performed by different surgeons, with different knowledge and exposure to different representations by Medtronic"); *Robinson v. Johnson & Johnson*, 2015 WL 3923292, at *5, *7 (Cal. Super. Ct. June 22, 2015) (same, because each plaintiff "had her own medical history and presenting problems and each patient had a doctor recommend this surgery in lieu of other therapies based on the specific facts known to such doctor"); *see also* Doc. 15-1 at 7 n.7 (discussing *Warner and Cumba*). Plaintiffs can derive no support from *Anaya v. Superior Ct.*, 160 Cal. App. 3d 228 (1984). Unlike the claims at issue here, *Anaya* involved claims by plaintiffs who were injured by chemical exposure at the *same* manufacturing facility.

⁴ So have many other courts. *See, e.g., Grynberg v. Ivanhoe Energy, Inc.*, 490 F. App'x 86, 92 n.4 (10th Cir. July 12, 2012); *Seiferth v. Helicopteros Atuneros, Inc.*, 472 F.3d 266, 275 (5th Cir. 2006); *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001).

1 *Testosterone Replacement Therapy Prods. Liab. Litig.*, 2016 WL 640520, at *4–*6 (N.D.
 2 Ill. Feb. 18, 2016) (holding that defendants’ Missouri contacts that gave rise to Missouri
 3 plaintiff’s claims were “inadequate to confer jurisdiction over defendants” with respect to
 4 Illinois plaintiff’s claims); *Robinson*, 2015 WL 3923292, at *5 (“That 67 plaintiffs have
 5 banded together . . . in one suit . . . does not change the analysis. . . . By the nature of the
 6 product, each plaintiff had a separate surgery by a specific treating physician for a
 7 specific set of complaints with a specific medical history. That the products and their
 8 disclosure warnings were the same or similar . . . is not enough to make the jurisdictional
 9 facts relevant to a California plaintiff applicable to a non-California plaintiff.”). Again,
 10 Plaintiffs have cited *no* contrary authority.

11 **B. The Court Should Dismiss The Claims Of The Non-California Plaintiffs**
 12 **As Against JRD For Lack Of Personal Jurisdiction.**

13 JRD is not subject to general or specific jurisdiction with respect to the Non-
 14 California Plaintiffs’ claims. *See* Defs.’ Mem. at 14. The Non-California Plaintiffs offer
 15 no argument in response. *See generally* Pls.’ Opp’n. They cannot satisfy their burden of
 16 establishing personal jurisdiction over JRD by ignoring Defendants’ arguments. *See, e.g.,*
 17 *Silva*, 2011 WL 7096576, at *3. To the extent the Non-California Plaintiffs intended to
 18 argue that JRD is subject to personal jurisdiction on an acting-in-concert and/or
 19 piggyback jurisdiction theory, their arguments fail for the reasons explained above.

20 **C. The Court Should Dismiss All Of Plaintiffs’ Claims Against TRL.**

21 As Defendants explained, *Sink v. Warner-Lambert Co.*, 2003 U.S. Dist. LEXIS
 22 27874 (C.D. Cal. Feb. 19, 2003) and *Skinner v. Warner-Lambert Co.*, 2003 WL
 23 25598915, at *1 (C.D. Cal. Apr. 28, 2003) stand for the proposition that clinical
 24 researchers like TRL are not subject to liability in pharmaceutical products liability cases.
 25 *See* Defs.’ Mem. at 14–15. Plaintiffs seek to discount these well-reasoned decisions by
 26 wrongly asserting that they lack “precedential value” or “discussion.” Pls.’ Opp’n at 18–
 27 19. They possess both. Further, Plaintiffs themselves cite *no* cases to support their
 28 argument that “there is no immunity for defendants who perform pharmaceutical research
 and are a subsidiary of another defendant.” Pls.’ Opp’n at 20. Simply saying it does not

1 make it so.⁵ Because Plaintiffs’ allegations against TRL are akin to those asserted against
 2 the researchers in *Sink* and *Skinner*, the Court should dismiss their claims against TRL.

3 Further, even if there were some basis for imposing liability on TRL as a
 4 pharmaceutical researcher—and there is *none*—Plaintiffs’ claims against TRL *still* fail
 5 because they are insufficiently pled. The FAC contains *no* allegations concerning *what*
 6 research TRL supposedly conducted or *how* TRL’s purported conduct caused Plaintiffs’
 7 alleged injuries.⁶ *See generally* FAC. Nor do Plaintiffs offer any explanation concerning
 8 TRL’s supposed research role. *See* Pls.’ Opp’n at 20–22. Instead, they rely on
 9 conclusory allegations concerning undifferentiated conduct by the collective
 10 “Defendants.” *Id.* at 21 (citing FAC ¶¶ 66–67, 201, 213, 247). But allegations that the
 11 collective “Defendants” designed, developed, manufactured, marketed, and distributed
 12 Invokana are insufficient to state a claim against TRL. *See, e.g., Aaron*, 2007 WL
 13 959083, at *16 & n.6; *see also* Doc. 15–1 at 10 n.11 (discussing additional authority). In
 14 the absence of any detail concerning *TRL’s* alleged role, Plaintiffs cannot state a claim
 15 against TRL even assuming that a cause of action for researcher liability were cognizable,
 16 which it is not. *See, e.g., Mountain Club Owner’s Ass’n v. Graybar Elec. Co.*, 2014 WL
 17 130767, at *2 (E.D. Cal. Jan. 14, 2014) (“‘A bare allegation that defendants were
 18 negligent in their design is an insufficient legal conclusion.’” (quoting *Fontalvo ex rel.*
 19 *Fontalvo v. Sikorsky Aircraft Corp.*, 2013 WL 4401437, at *5 (S.D. Cal. Aug. 15,
 20 2013))).

21
 22 ⁵ While Plaintiffs assert that TRL is a subsidiary of MTPC (*see* Pls.’ Opp’n at 19), the
 23 FAC contains *no* such allegation. *See generally* FAC. Even if Plaintiffs’ assertion were
 24 true, Plaintiffs do not explain *why* TRL’s relationship to MTPC should make any
 25 difference to whether TRL can be subject to liability for its alleged research role.

26 ⁶ The lack of this required factual detail is entirely unsurprising, because TRL had *no* role
 27 in conducting any such research, nor did it have *any* role in the development,
 28 manufacture, or distribution of the drug. *See* Defs.’ Mem. at 14 (discussing Sakurai
 Decl.). Further, Plaintiffs’ unfounded, vague, and conclusory allegation that TRL
 “conducts pharmaceutical research, including with respect to” Invokana does *not* show
 that TRL “possibly” is subject to liability. Pls.’ Opp’n at 21. And in any event, a
 plaintiff does *not* state a plausible claim merely by alleging facts showing a “possible”
 entitlement to relief. *See, e.g., Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining
 that where complaint pleads facts that are “merely consistent with a defendant’s liability,
 it stops short of the line between possibility and plausibility of entitlement to relief”).

D. The Court Should Dismiss Plaintiffs’ Design Defect-Based Claims Because They Are Preempted By Federal Law.

Plaintiffs respond to Defendants’ preemption arguments by referring to their prior briefing. *See* Pls.’ Opp’n at 22. For the Court’s convenience, Defendants will do the same. As explained, Plaintiffs’ arguments lack merit. *See* Doc. 24 at 9–11.

Plaintiffs’ attempt to distinguish *Fleming v. Janssen Pharmaceuticals, Inc.*, --- F. Supp. 3d ---, 2016 WL 3180299 (W.D. Tenn. June 6, 2016) fares no better. Contrary to their suggestion, the result in *Fleming* is *not* unique to the Sixth Circuit. *See* Pls.’ Opp’n at 23 (arguing that *Fleming* court “felt compelled to follow *Yates*”). In finding preemption, the *Fleming* court applied the Supreme Court’s reasoning in *Mensing* and *Bartlett* and relied on cases from “[o]ther district courts,” including *Batoh v. McNeil-PPC, Inc.*, --- F. Supp. 3d ---, 2016 WL 922779 (D. Conn. Mar. 10, 2016). 2016 WL 3180299, at *4–*5. Further, the fact that the Sixth Circuit decided *Yates* at the summary judgment stage (*see* Pls.’ Opp’n at 23) is irrelevant because *Fleming* and other cases demonstrate that this Court can and should decide the preemption challenge at issue here at the *pleading* stage. *See* Doc. 15–1 at 20 (discussing *Mensing*, *Barcal*, *Amos*, and *Thompson*).

In fact, just last week, the Northern District of Georgia confirmed—at the pleading stage—that the design claims of yet another Invokana plaintiff were preempted to the extent based on an alleged failure to change Invokana’s chemical design. *See Brazil v. Janssen Research & Development LLC*, --- F. Supp. 3d ---, 2016 WL 3748771, at *10 (N.D. Ga. July 11, 2016) (“Any claim by Plaintiff that Defendants should change the formulation of Invokana is preempted by FDA regulations.”). Moreover, like the *Fleming* court, the *Brazil* court rejected the plaintiff’s argument that her claim was not preempted because it was premised on a failure to change Invokana’s design *before* FDA approval. *See id.* at *11 (“This original design theory of liability makes little sense in the face of the Supreme Court’s precedents. The Supreme Court has repeatedly characterized the state tort law at issue in this case as a duty to make changes or as a

remedial effort.”). This Court should follow *Fleming* and *Brazil* and the many other decisions demonstrating that Plaintiffs’ design defect claims are preempted. *See* Doc. 15–1 at 21–23 & n.21 (discussing additional authority).

E. All Of Plaintiffs’ Claims Against Johnson & Johnson, Ortho, MTPD, And TRL Are Preempted By Federal Law.

Plaintiffs offer no response to Defendants’ argument that all of their claims against Johnson & Johnson, Ortho, MTPD, and TRL are preempted and should be dismissed with prejudice because none of these Defendants is the NDA applicant. *Compare* Defs.’ Mem. at 20, *with* Pls.’ Opp’n at 22–23. Just last week, the *Brazil* court dismissed another Invokana plaintiff’s failure-to-warn claims against Ortho on this very basis. *See Brazil*, 2016 WL 3748771, at *11. Relying on *In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*, 756 F.3d 917 (6th Cir. 2014), the court explained that “[w]hen a company does not have the NDA, it has ‘no more power to change the label’ of a drug than a generic manufacturer.” *Brazil*, 2016 WL 3748771, at *11 (quoting *Darvocet*, 756 F.3d at 940)). Because Ortho “could not independently do under federal law what state law requires of it,” the court held that “the state law claims brought against it are preempted.” *Id.* (quoting *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012)).⁷

The same reasoning compels the dismissal of Plaintiffs’ claims against Johnson & Johnson, Ortho, MTPD, and TRL.⁸ Because these Defendants could not independently alter the design or labeling of Invokana, Plaintiffs’ claims against them—which all are premised on purported failures to properly design and label the drug—are preempted and should be dismissed with prejudice. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579

⁷ Plaintiffs cannot avoid dismissal by feigning that they did not “comprehend” Defendants’ preemption argument. Pls.’ Opp’n at 23; *see also, e.g., Silva*, 2011 WL 7096576, at *3 (explaining that “a court may treat those arguments that the plaintiff failed to address as conceded”). The *Brazil* court understood the argument perfectly well.

⁸ The *Brazil* court did not need to apply its ruling to Johnson & Johnson because it previously dismissed Johnson & Johnson due to lack of personal jurisdiction. *See* Doc. 25–1 at 6–7. Further, neither MTPD nor TRL were defendants in *Brazil*. But the reasoning that led the court to dismiss Ortho unquestionably applies to Johnson & Johnson, MTPD, and TRL.

(2011) (“The question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it.”).

F. The Court Should Dismiss Mr. Dumas’s Claims As Insufficiently Pled.

Plaintiffs devote five pages of their Opposition to rehashing arguments that they previously briefed. *See* Pls.’ Opp’n at 13–17; *see also* Doc. 23 at 10–15. For the Court’s convenience, Defendants will not do that but instead will incorporate their responsive arguments herein by reference. *See* Doc. 24 at 4–6.

In addition, Defendants explained that *Fleming*—like *Brazil* and *Guidry*—compels the dismissal of Mr. Dumas’s strict liability design defect and negligent design claims. *See* Defs.’ Mem. at 17–18. Plaintiffs do not address *Guidry*, and they mistakenly assert that *Fleming* and *Brazil* are distinguishable because they involved Tennessee and Georgia law, respectively. *See* Pls.’ Opp’n at 6–7. In fact, all three decisions are highly relevant because they turn on application of the federal *Twombly-Iqbal* pleading standard, *not* any nuances in state law. Plaintiffs say that Mr. Dumas’s design claims are pled with greater particularity than the claims in *Fleming* and *Brazil*. But to support that argument, they simply point to a handful of wholly conclusory allegations that are devoid of *any* meaningful detail and that are inappropriately directed to the collective “Defendants.” *Id.* at 6 (citing FAC ¶¶ 49–52, 84–87, 126–31). These are the *same* type of conclusory allegations that the courts in *Fleming* and *Brazil* correctly rejected. In fact, in dismissing the plaintiff’s amended design defect claims, the *Brazil* court relied on *Fleming* for the common-sense proposition that “[m]erely describing how Invokana works is insufficient to describe a defect.” 2016 WL 3748771, at *6. The Court should follow *Brazil*, *Fleming*, and *Guidry* and dismiss Mr. Dumas’s design claims.

As Defendants also explained, *Fleming* and *Guidry* support dismissal of Mr. Dumas’s failure-to-warn-based claims—which depend on an alleged failure to warn about a risk of kidney failure. *See* Defs.’ Mem. at 18; Doc. 15–1 at 12–14. Plaintiffs do not address this argument other than to suggest that Mr. Dumas’s claims are pled “with particularity that may be absent from *Fleming*.” Pls.’ Opp’n at 7; *see also id.* at 13–16

(discussing Plaintiffs' claims generally rather than *Mr. Dumas's* claims). But they do *not* explain *how* his claims differ from the claims rejected in *Fleming* and *Guidry*.

In short, the Court should dismiss Mr. Dumas's claims as insufficiently pled.²

G. The Court Should Deny Plaintiffs' Alternative Requests For Relief.

If Plaintiffs wish to amend their pleading for a second time, they should file an appropriate motion with the Court. *See Gardner v. CafePress, Inc.*, 2014 WL 7183704, at *4 (S.D. Cal. Dec. 16, 2014) ("As Plaintiff has sought leave to amend in an opposition rather than in a motion, the Court declines to consider the issue of leave to amend.").

Likewise, Plaintiffs have not demonstrated that they are entitled to discovery into jurisdictional and preemption issues. They have failed sufficiently to allege that their claims arise out of or relate to any contacts that Johnson & Johnson, Ortho, and MTPD purposely directed at California to warrant jurisdictional discovery. In addition, no amount of "discovery into the science underlying Invokana" will aid in resolving the purely legal preemption issue before the Court. Further, Plaintiffs have not made a proper request for discovery. *See, e.g., Mother Doe I v. Al Maktoum*, 632 F. Supp. 2d 1130, 1146 (S.D. Fla. July 30, 2007) (explaining that request for discovery in opposition memorandum is "not a substitute for the issuance of discovery requests").¹⁰

III. CONCLUSION

For the reasons stated, the Court should grant Defendants' Motion in its entirety.

² Contrary to Plaintiffs' argument (*see* Pls.' Opp'n at 12), the conclusory allegations in paragraph 68 of the FAC are insufficient to state a plausible manufacturing defect claim against Ortho. *See, e.g., Brazil*, 2016 WL 3748771, at *5-*6 (dismissing manufacturing defect claim in another Invokana case as insufficiently pled); *Guidry v. Janssen Pharms., Inc.*, 2016 WL 633673, at *4 (E.D. La. Feb. 17, 2016) (same). Any such claim also is preempted by federal law. As a non-NDA holder, Ortho had no authority unilaterally to change the "manufacturing processes" or "materials" used in the production of Invokana. *See supra* Part II.E.; *see also* Doc. at 15-1 at 24 & n.23.

¹⁰ If the Court were to allow any such discovery, it must be narrowly tailored so it is "proportional to the needs of the case," Fed. R. Civ. P. 26(b)(1), and Plaintiffs should pay for it. *See* Fed. R. Civ. P. 26(c)(1)(B) (permitting "allocation of expenses" to requesting party to protect against "undue burden or expense"). Shifting the cost of discovery to Plaintiffs would be appropriate here, because Plaintiffs have failed to identify—let alone with the requisite specificity—what discovery they supposedly need or how they expect to establish facts to support jurisdiction. *See, e.g., Ashmore v. Allied Energy, Inc.*, 2016 WL 301169, at *2 (D.S.C. Jan. 25, 2016) (discussing factors governing cost-shifting).

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